

RegJoint™ implant shall not be used after labeled expiration date or if the double blister package is damaged. Resterilization of RegJoint™ implant is not possible by any method. If you receive a damaged package, contact your local distributor or Scaffdex Oy directly.

Swelling, haematoma and stiffness of the operated joint are common findings after this kind of an operation. The swelling usually decreases in 4-6 weeks. Physiotherapy and manipulation of the joints improve mobility and decrease stiffness.

A short period of mild pain has been noticed in some patients between 6-12 or 18-24 months after the operation. This phenomenon is connected with the active resorption period of the implant and usually does not require any specific action or only some pain medication according to the need.

In some patients minor osteolytic changes that confine to joint surface areas can be detected in radiographs approximately 6 months after the operation. Osteolytic changes do not seem to progress or to cause any clinical signs, but it is in most cases merely a radiographic finding.

## Surgical technique

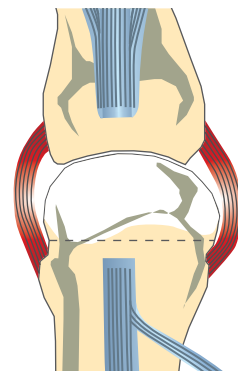
It is the operating surgeon's responsibility to get familiar with RegJoint™ implant and different surgical techniques. Surgical technique instructions and videos are available from Scaffdex Oy: [www.scaffdex.com](http://www.scaffdex.com) or [orders@scaffdex.com](mailto:orders@scaffdex.com). Information of training courses is available on [www.scaffdex.com](http://www.scaffdex.com) or from local distributors.

Scaffdex Oy as the manufacturer of this device, does not practice medicine and does not recommend these or any other surgical technique or rehabilitation program for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

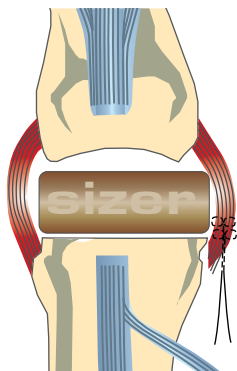
## Metacarpophalangeal (MCP II-V) joints

- Surgical technique video is available in website [www.scaffdex.com](http://www.scaffdex.com)
- The surgery is performed using a tourniquet and a bloodless field.
- One dose of prophylactic antibiotic is recommended for preoperative prophylaxis.
- A dorsal transverse skin incision.
- Opening of the extensor hood longitudinally on the radial or ulnar side of the extensor tendon.
- In case of subluxated tendon the ulnar sagittal band and transverse fibres are divided to mobilize the tendon in a radial direction.

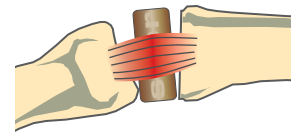
- If necessary, the radial sagittal band can be overlapped in the end of the operation to centralize the extensor tendon.
- The extensor hood and capsule are separated.
- The joint capsule is opened longitudinally in midline and synovectomy is carried out.
- The metacarpal head is resected just distal to the collateral insertions. Picture 1. The resection line is equal to Swanson arthroplasty.
- The ulnar collateral and if necessary the radial ligaments are released from their metacarpal origins and picked up by the absorbable holding core suture.
- The palmar joint capsule is detached from the metacarpal and the palmar plate released by longitudinal incision to correct the palmar subluxation in order to lift the palmar edge of the proximal phalanx to the level of the dorsal edge of the metacarpal bone.
- The ulnar intrinsic muscles are also divided if needed in order to correct palmar subluxation or release ulnar tightness.
- The abductor digiti minimi of the little (fifth) finger is divided.
- A crossed intrinsic transfer is carried out if the radial collateral ligament is markedly weakened.
- RegJoint™ sizers can be used to evaluate the correct size of the implant. The ideal size completely covers the bone end. Picture 2.



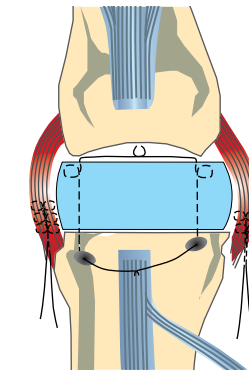
Picture 1. Metacarpal resection line.



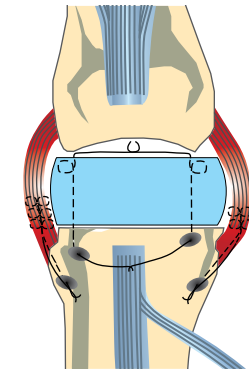
Picture 2. RegJoint™ sizer evaluating the optimal coverage of the metacarpal bone end in MCP joint.



Picture 3. Testing sizer in its place.



Picture 4. RegJoint fixation with resorbable sutures.



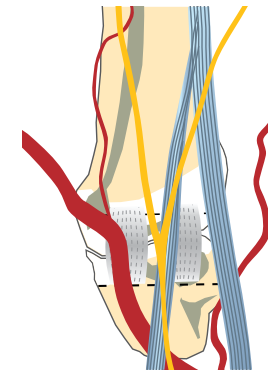
Picture 5. Ligament reinsertion.

- Wetting of RegJoint implant with sterile saline prior installation may accelerate population of the structure by fibroblasts.
- Extension and flexion are tested with a RegJoint™ sizer in its place. Picture 3.
- RegJoint™ is fixed with resorbable sutures (e.g. PDS, 2-0, UCL needle ☉) passing through the metacarpal bone and via the distal palmar plate. Picture 4.
- Balancing and tightening of the collateral ligaments is done by reinsertion of the ligaments at a more proximal insertion site and slightly dorsally through drill holes in the distal metacarpal bone. Picture 5.
- Ulnar collateral ligament is re-inserted in order to improve soft tissue balance adjustment and to counteract tendency to palmar subluxation.

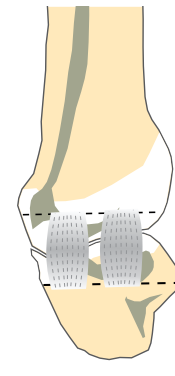
- Extensor tendon is centralized.
- The joint and soft tissues are closed in routine manner. Tightening of the skin should be avoided.
- Operated joints are supported with a palmar static splint for 10 days.
- Active and passive range of movement exercises are assisted with low-profile dynamic dorsal splinting starting 10 days postoperatively and continued for up to 12 weeks.
- Light activities of daily living are allowed immediately after the use of dynamic splint is initiated.
- Rehabilitation and physiotherapy are planned individually for each patient.

## Revisions in MCP joints

- In revision cases, old prosthesis as well as scar and granulation tissue are carefully removed from inside the metacarpal and phalangeal bones.
- The volar plates are released when necessary.
- Bone grafts are prepared from the resected metacarpal heads, from e.g. siliac bone or from allogeneic bone or bone substitute.
- Bone grafts are morcelised into 2-3 mm chips which are packed inside the metacarpal and phalangeal bones, leaving the juxta-articular portion empty at this stage.
- Two to three micro burr holes are drilled in the distal dorsal aspect of the metacarpal bones for later reattachment of the collateral ligaments.
- Wetting of RegJoint implant with sterile saline prior installation may accelerate population of the structure by fibroblasts.
- The scaffold is inserted into the joint space and fixed in place with resorbable sutures (e.g. PDS 2-0, UCL needle ☉) passed through distal metacarpal burr holes and picking up the volar plate adjacent to the base of the phalanx.
- Bone packing will be completed up to the level of the bone ends.
- After bone packing, the implant fixation suture is tightened.
- Collateral ligaments are tightened by suturing their proximal ends to the metacarpal burr holes with absorbable sutures while balancing the finger alignment.
- Suction drains can be inserted in those cases in which revisions of all of the metacarpophalangeal joints will be carried out
- Closure as in primary operations
- Rehabilitation and physiotherapy are planned individually for each patient.



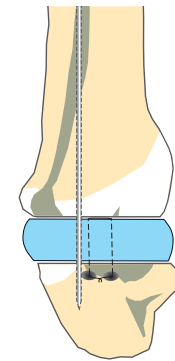
Picture 6. Radial nerve and the deep branch of the radial artery.



Picture 7. Resection lines.

## The first carpometacarpal (CMC I) joint

- Surgical technique videos for total trapeziectomy and minimally invasive hemitrapeziectomy are available in website [www.scaffdex.com](http://www.scaffdex.com)
- Surgery is performed using a tourniquet and a bloodless field
- One dose of prophylactic antibiotic is recommended for preoperative prophylaxis
- Palmar or dorsal joint opening can be used.
- In dorsoradial longitudinal incision preserving branches of superficial radial nerve and the deep branch of the radial artery. Picture 6.
- The first carpometacarpal (CMC) joint is identified, the capsule released and opened dorsoradially
- The first metacarpal is released carefully proximally to correct the prevailing adduction contracture
- The resection of the proximal part of the first metacarpal is done by using an oscillating saw. The resection line of the proximal part of the first metacarpal is perpendicular with respect to the metacarpal. The resection of the cartilage surface of the trapezium is performed using a curette or an oscillating saw. Picture 7.
- Other options are partial or complete trapezium resections without metacarpal resection. The extension of the resection is proportional to the joint laxity.
- Perform synovectomy and revise osteophytes.



Picture 8. Temporary K-wire fixation and transosseous sutures.

- RegJoint™ sizers can be used to evaluate the correct size of the implant. Ideal size completely covers the bone end. Picture 2.
- RegJoint™ is fixed with transosseous resorbable sutures (e.g. PDS 2-0, with UCL needle ☉). Alternatively, the scaffold can be fixed into the joint capsule or with the surrounded flexor carpi radialis tendon.
- Wetting of RegJoint implant with sterile saline prior installation may accelerate population of the structure by fibroblasts.
- Alternatively, RegJoint™ can also be fixed with a temporary K-wire going through the first metacarpal (or the whole thumb) to the resected joint line piercing the implant and trapezium up to the carpals. Picture 8.
- If additional support is needed a tendon interposition from flexor carpi radialis, abductor or extensor tendons can be used.
- A careful reconstruction of the joint capsule is performed using absorbable suture material. Duplication can be used if needed.
- The subcutis and skin are closed in routine manner. Tightening of skin shall be avoided.
- Soft bandage or a temporary plaster for immobilization of the thumb can be used.
- On the second or third post-operative day the plaster is removed and an orthose (e.g. Hexalite, neoprene or thermoplastic material) can be applied for 4-6 weeks.
- External K-wire is removed after 3-4 weeks.
- Range of motion exercises are allowed after 4-6 weeks using a special training splint.
- After 6 weeks a functional abduction splint is applied if needed.
- Rehabilitation and physiotherapy are planned individually for each patient.

RegJoint™ is indicated for arthroplasties in small joints in hands and feet. Specific target joints are metatarsophalangeal I-V, (MTP I-V), carpometacarpal I (CMC I), metacarpophalangeal II-V (MCP II-V) and proximal interphalangeal (PIP) joints.

RegJoint™ is manufactured of bioabsorbable poly-96L/4D-lactide copolymer fibre. It is a porous, disc like implant. RegJoint™ sizers are available to help to choose the optimal size of RegJoint™ for each patient. RegJoint™ product and size selections are presented in Tables 1 and 2. RegJoint™ loses its initial strength during 15 to 24 weeks in vivo, with complete strength loss and resorption on average within 2-3 years, depending on the patient variables. The fibres in the RegJoint™-implant offer an attachment base for the patient's connective tissue cells and the porous structure enhances the welfare of the neo tissue. RegJoint™ provides temporary support and guidance for the fibrotic tissue in-growth. It allows a gradual optimized replacement of the implant with fibrous tissue providing a flexible and durable pseudo joint.

Implanting RegJoint™ does not require any specific instrumentation. All used instruments need to be appropriately cleaned and sterilized before use. All sutures and other materials need to be sterile.

RegJoint™ is sterilized by gamma irradiation and is supplied sterile and ready for use. RegJoint™ shall not be re-sterilized by any method.

## Product selection

Table 1. Available RegJoint™ product sizes and reference numbers.

Reference number	Diameter (mm)	Height (mm)
RG0001	8	3.6
RG0002	10	4.0
RG0003	12	4.0
RG0004	14	4.5
RG0005	16	4.5
RG0006	18	4.5
RG0007	20	4.5

Table 2. Available RegJoint™ sizers and reference numbers.

Reference number	Diameter (mm)	Height (mm)
S01	8	3.8
S02	10	4.4
S03	12	4.4
S04	14	4.9
S05	16	4.9
S06	18	4.9
S07	20	4.9

## Guidance for patient selection

RegJoint™ implant is applicable for patients with destruction of joints in hand or foot due to e.g. rheumatoid arthritis or osteoarthritis. RegJoint™ -operation is indicated when the disease disturbs normal daily activities due to pain or functional limitations that cannot be controlled with conservative methods. In controlled, randomized clinical trials of RegJoint™, the time period from the diagnosis until the operation varied between 1 - 60 years for rheumatoid arthritis and between 1 - 42 years for osteoarthritis patients. Average duration of the disease in concern before RegJoint™ operation is presented in Table 3.

Patient's lactose intolerance, known sensitivity to suture materials, many parallel allergies, appearance of bone cysts pre-op nearby implantation site or earlier foreign body reactions with implants may influence the clinical result with RegJoint implant.

Table 3. Average duration from the diagnosis until the RegJoint™ operation in clinical trials.

Limb	Diagnosis	Average duration (years)	All
Hand	Rheumatoid arthritis	20,7	17,8
	Osteoarthritis	11,6	
Foot	Rheumatoid arthritis	17,9	14,6
	Osteoarthritis	14,6	

## Contraindications

RegJoint™ is contraindicated in the case of

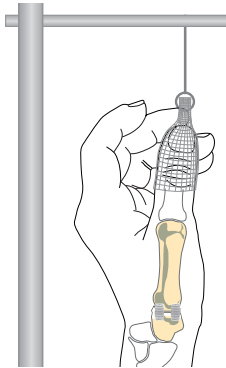
- 1) hypersensitivity to the implant material. If necessary, hypersensitivity shall be tested out prior to implantation,
- 2) active sepsis,
- 3) conditions that limit a patient's ability or willingness to restrict activities or comply with other instructions during the healing and rehabilitation period.
- 4) RegJoint™ is not intended in operations of knees, hips or spine.

## Warnings

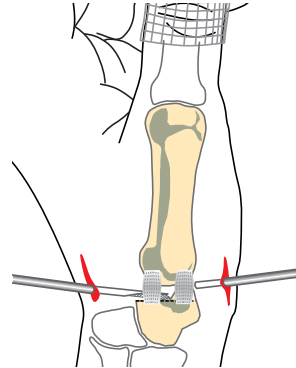
RegJoint™ implant shall not be cut or reshaped by any method due to the risk of unraveling the knitted structure.

## The first carpometacarpal (CMC I) joint arthroscopic operation

- Hang the thumb on a holder pulling it lightly to open the joint gap. Picture 9.
- Create two portals; dorsal and radio palmar. One is for optics and the other for instruments.
- Identify the concave shaped surface of trapezium to assure you are working in the right joint gap. In case of doubt assure the correct position with fluoroscopy.
- Make synovectomy if needed.
- Resect the complete distal cartilage surface of the trapezium with a small burr via dorsal and palmar portals in order to create a smooth and even surface. In addition to the cartilage resection in hemi trapezectomy the bone resection depth should be around 2-3 mm at maximum. The surface of the metacarpal bone remains intact. Assure the correct resection depth with fluoroscopy. Picture 10.
- For RegJoint™ implantation extend the incision of the dorsal portal and open the joint capsule. It is important not to squeeze the implant during the implantation so that RegJoint™ maintains its porosity also in the joint gap.
- Wetting of RegJoint implant with sterile saline prior installation may accelerate population of the structure by fibroblasts.

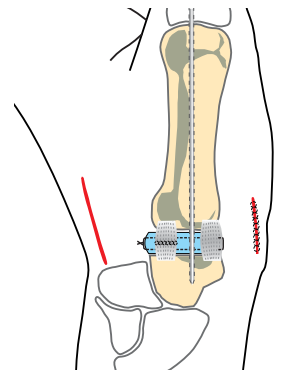


Picture 9. A holder for the thumb.



Picture 10. Burring an even surface on trapezium.

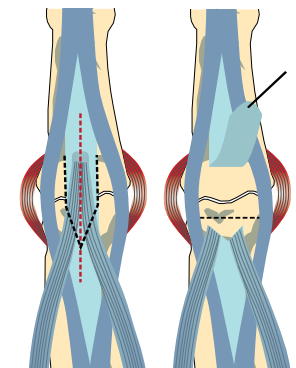
- Fix RegJoint™ to the joint capsule in a correct position and then close the capsule. The implant can also be fixed with temporary K-wire going through the first metacarpal (or whole thumb) piercing the implant and trapezium up to the carpals. Picture 11.
- When choosing the RegJoint™ size avoid to over fill the joint gap. The correct implant size is always chosen individually; for this indication the most commonly used RegJoint™ sizes are 12-16 mm.
- After closing the skin wounds a padded glass fiber splint is laid to support the thumb in an abduction. In 4 weeks remove the splint and start the rehab exercises. Rehabilitation and physiotherapy are planned individually for each patient.



Picture 11. RegJoint™ fixation to the joint capsule and with temporary K-wire.

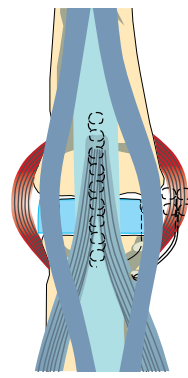
## Proximal interphalangeal (PIP) joint

- Volar or dorsal incisions can be used. In picture 12 the options of dorsal openings.
- Exposure of the joint in midline or Chamay opening.
- Synovectomy.
- Bone resection of the proximal phalanx:
  - evaluate joint tightness before resection
  - carefully remove palmar osteophytes
- If needed:
  - collateral tightening
  - extensor reconstruction



Picture 12. Incision options; longitudinal (red) and v-shaped Chamay opening.

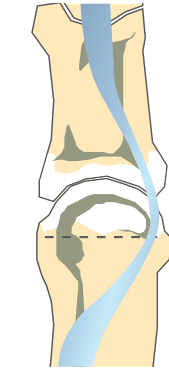
- Wetting of RegJoint implant with sterile saline prior installation may accelerate population of the structure by fibroblasts.
- RegJoint™ can be fixed with absorbable sutures (e.g. 2-0 PDS with UCL needle ⊙) via bone canals to the end of proximal phalanx.
- Joint capsule and extensor apparatus are closed. Picture 13.
- Rehabilitation and physiotherapy are planned individually for each patient.



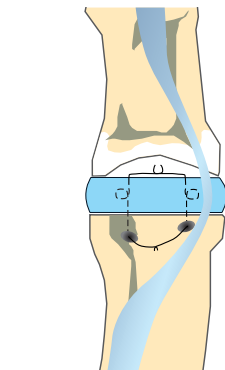
Picture 13. Implant fixed, collaterals tightened and extensor closed.

## The first metatarsal (MTP I) joint

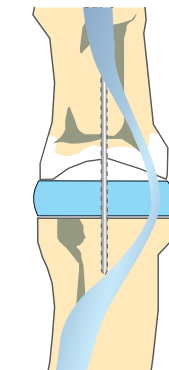
- Surgical technique video is available in website [www.scaffdex.com](http://www.scaffdex.com)
- The surgery is performed using a tourniquet and a bloodless field.
- One dose of prophylactic antibiotic is recommended for preoperative prophylaxis.
- Medial skin incision, excise extra union and skin if needed.
- Extensor tendon might be lengthened if very tight.
- Excise exostosis and osteophytes and perform synovectomy if needed.
- The bone is resected 4-8 mm from the first metatarsal head perpendicular to metatarsal axis using an oscillating saw. Leave the cartilage on the articular surface of the first proximal phalanx. Picture 14.
- RegJoint™ sizes are used for evaluating the correct implant size. The ideal size completely covers the bone end but does not significantly exceed the cortical bone edges. Picture 2.



Picture 14. Metatarsal resection line.



Picture 15. Fixation with resorbable sutures.

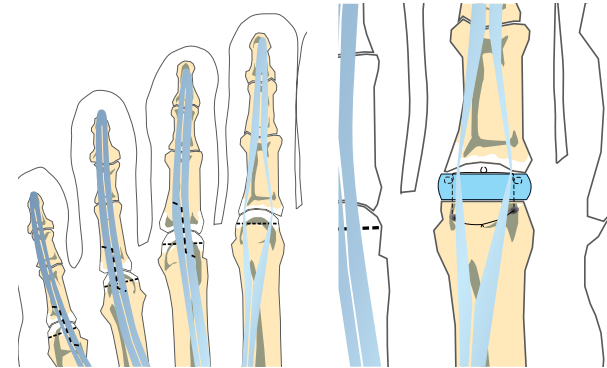


Picture 16. K-wire fixation.

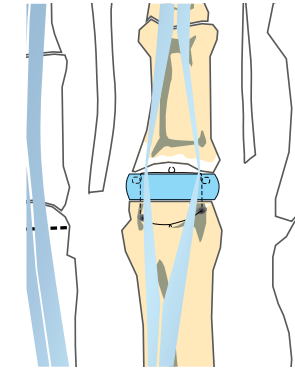
- Wetting of RegJoint implant with sterile saline prior installation may accelerate population of the structure by fibroblasts.
- RegJoint™ is inserted on the metatarsal head.
- RegJoint™ can be sutured to the metatarsal head through bone canals with resorbable sutures (e.g. PDS 2-0, with UCL needle ⊙). Picture 15.
- This technique is especially suitable in cases with minimal axis deviation.
- Alternatively, an external K-wire can be inserted from the tip of the big toe through the first MTP joint in the inside-out-in technique, fixating the implant and leading into the first metatarsal bone. Cut and bend the K-wire and leave it external at the end of the toe. Picture 16.
- Medial joint capsule is closed tightly. Additional soft tissue is released, if the ideal position of the toe requires it.
- Close carefully retinacular tissue.
- Subcutis and skin closure in routine manner. Avoid tightening of soft tissue.
- A soft bandage is applied.
- External wire is drawn away after 2-4 weeks and a proper mobilization is encouraged in the 5th week. This applies to both fixation techniques.
- Support under the heel (leaving the resected metatarsal free) and the use of crutches are recommended during the first two weeks.
- Supporting footwear with firm sole is used for 4-6 weeks.
- Rehabilitation and physiotherapy are planned individually for each patient.

## Other metatarsal (MTP II-V) joints

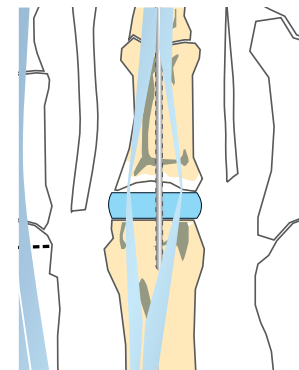
- Surgical technique video is available in website [www.scaffdex.com](http://www.scaffdex.com)
- The surgery is performed using a tourniquet and a bloodless field.
- One dose of prophylactic antibiotic is recommended for preoperative prophylaxis.
- Transversal or two longitudinal skin incisions are applied.
- Exposure of the joint between extensor tendons.
- Extensor tendons can be lengthened, if necessary. Picture 17.
- Synovectomy is performed if needed, collateral ligaments are released and metatarsal heads resected. Picture 17.
- The first and second metatarsal stumps are osteotomised at about equal length, and no stump projects beyond a gently curving line of resection, which ends at the fifth metatarsal.
- In case of a single metatarsal operation osteophytes are excised and the metatarsal head is remodelled.
- Plantar joint capsule is released from the metatarsal bone.
- RegJoint™ sizes are used for the evaluation of the correct implant size. The ideal size completely covers the bone end but does not significantly exceed the cortical bone edges. Picture 2.
- Wetting of RegJoint implant with sterile saline prior installation may accelerate population of the structure by fibroblasts.



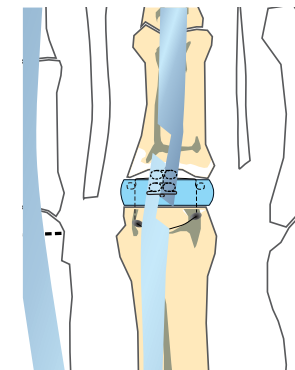
Picture 17. Extensor tendons' lengthening and metatarsal heads' resection line.



Picture 18. Scaffold sutured to the metatarsal head through bone canals.



Picture 19. Fixation with a K-wire.



Picture 20. L-shaped lengthening of the extensor tendon.

- RegJoint™ is positioned into the joint space.
- RegJoint™ can be sutured to the metatarsal head through bone canals with resorbable sutures (e.g. PDS 2-0 with UCL-needle ⊙). Picture 18.
- Wetting of RegJoint implant with sterile saline prior installation may accelerate population of the structure by fibroblasts.
- Alternatively, fixation with a K-wire from the tip of the toe to metatarsal bone via bone canals (picture 19) using the inside-out-in technique. K-wire is removed after 2-4 weeks.
- Extensor tendon adaptation with resorbable suture. If needed extensor brevis tendon can be cut off or extensor lengthening can be performed (commonly L-shaped). Picture 20.
- Skin is closed in routine manner, tightening shall be avoided.
- Support under the heel (leaving the resected metatarsals free) and the use of crutches are recommended during the first two weeks.
- Supporting footwear with firm sole is used for 4-6 weeks, gradual mobilization of the toes after 4 weeks.
- Rehabilitation and physiotherapy are planned individually for each patient.

## Follow-up visits after surgery

General follow-up routine and time points for each type of surgery are described in instructions concerning each joint. These are typically related to the usage of bandage or splints or the removal of K-wire. An average follow-up and rehabilitation period is 2-3 months and is supervised by a doctor or by an occupational therapist depending on each hospital's routines. Additional control visits are scheduled if necessary. The surgeon who performs any implant procedure is responsible for determining and using the appropriate rehabilitation program for each patient.

Any serious incident that has occurred in relation to the device should be reported to Scaffdex Oy and the competent authority of the Member State in which the patient and/or health care institution is established.

## Symbols in labels



Unique device identifier



Do not use if package is damaged and consult instructions for use



Medical device



Do not re-sterilize



Keep dry



Prescription only - device restricted to use by or on the order of a physician



Do not re-use



20YY-MM-DD Use-by date



25°C/77°F Upper limit of temperature



Consult instructions for use



Sterilized using irradiation



Manufacturer



Batch code



Catalogue number



Caution



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